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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/844,187	04/26/2001	Thomas M. Baer	14255-034001 / ARC01-2001	2124
26161	7590	12/27/2007		EXAMINER
FISH & RICHARDSON PC				LUDLOW, JAN M
P.O. BOX 1022				
MINNEAPOLIS, MN 55440-1022			ART UNIT	PAPER NUMBER
			1797	
				MAIL DATE
				DELIVERY MODE
			12/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/844,187	BAER ET AL.	
	Examiner	Art Unit	
	Jan M. Ludlow	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 05 October 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,2,4-13,79-82 and 93-108 is/are pending in the application.
- 4a) Of the above claim(s) 5-13,79-82,93-99,101-103 and 105-108 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2,4,100 and 104 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 26 April 2001 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-3, 100 are rejected under 35 U.S.C. 103(a) as being obvious over Ito (5063025) in view of Golias (4,341,635).

Ito teaches a carrier 14 with bottom surface near 13a in extraction device 11, 12 that is open at both ends and forms a reservoir. See Figure 1. When the carrier 14 is fully depressed, the edges of the bottom of 13a abut the ends of tube 11, excluding the edges of 13a from the reservoir in 12. A volume of 5 microliters is disclosed (col. 1, line 30). It is the examiner's position that the carrier inherently seals the first opening in that the device would not function as a syringe if no seal were present. See also Figure 7 for an alternative prior art embodiment. With respect to adaptation for mating, the device is structurally capable of mating with another vessel of suitable size and configuration.

Ito fails to teach a flange at the first end.

Golias teaches a microsyringe similar to Ito. A flange 70 is provided for gripping the syringe.

It would have been obvious to provide a flange on the upper end of the syringe body of Ito (instant extraction vessel) in order to provide a gripping surface as taught by Golias.

6. Claim 1-2, 4, 100, 104 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO99/17094 (hereafter "WO") and further in view of Silverstolpe (2,649,245).

WO teaches a carrier 1120 with film 1130 and rim 1150 which contacts the sample, but not the interior of extraction device 1110, because it seals against shoulder 1140, permitting specifically bound cells in the center of the film to communicate with the vessel reservoir and non-specifically bound cells clinging to the ridge to be excluded from the reservoir (pp. 20-21, Figure 11A-D). The extraction device has a top opening for receiving the carrier and a conduit (passageway) leading to the second (bottom) end.

7. WO fails to teach an opening in the second end or the flange.

8. Silverstolpe teaches a centrifuge tube having a cylindrical upper portion and tapered bottom portion (Fig. 1) similar to the vessel of WO. The bottom end of the tube has an opening that is closed by a stopper 11 for accessing the bottom end of the tube. The top of the tube may be provided with a flange 20.

9. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the tube of WO with an open bottom end in order to withdraw concentrated fluids or solids from the bottom of the tube as taught by Silverstolpe. It would have been obvious to provide a flange on the microcentrifuge tube of WO in order to provide the flange of Silverstolpe, which one of ordinary skill would understand provides a gripping surface and/or a stop surface for insertion into a rack or the like. With respect to claim 2, it would have been obvious to make the vessel

of suitable size to handle very small samples in order to minimize the use and disposal of costly and/or hazardous reagents. With respect to adaptation for mating, the device is structurally capable of mating with another vessel of suitable size and configuration.

10. Applicant's arguments filed October 5, 2007 have been fully considered but they are not persuasive.

11. Applicant argues that the lower end of the extraction vessel of Ito is not adapted for mating, but, clearly, it is adapted as claimed, e.g., the needle is "adapted" for insertion through a septum of a sealed sample vial to couple the conduit to the contents of the vial or vessel. The flange is taught by Golias.

12. Applicant argues that WO does not teach a flange or adaptation for mating and that Silverstolpe does not remedy this deficiency, but this is simply not so. First, applicant argues that the collar of Silverstolpe is somehow not the same as the flange claimed. How so? They are both flanges at the upper end of a tube. If the flange instantly *disclosed* differs from that of Silverstolpe, the difference is not reflected in the claims, which merely require "at least one flange". Similarly, "adapted to mate" is disclosed by Silverstolpe, in that the open end of the tube with the stopper removed can be, e.g., inserted into a vessel having an inner diameter matched to the outer diameter of the centrifuge tube. "Adapted to mate" is a nearly meaningless limitation without specifying what the adaptation is.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (571) 272-1260. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Jan M. Ludlow
Primary Examiner
Art Unit 1743

JML

December 17, 2007